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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,683	11/04/2003	Robert C. Brunham	1038-1273 MIS:ah	2991

7590 02/27/2006

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/699,683	BRUNHAM ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-22 and 24-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-22 and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 19-22, 24-28 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 6, 2005 has been entered.

2. ***Rejections Withdrawn:*** Claims 19, 22, 25, 27-28 rejected under 35 U.S.C. 102(e) as being anticipated by Gurtiss III (US Pat. 5,389,368), is herein withdrawn in light of the amendment of claim 19 to require the expression of the nucleic acid to be expressed by the host and not the attenuated strain, to which the strain is administered.

3. ***Rejections Withdrawn:*** Claims 20-21, 24, and 26 rejected under 35 U.S.C. 103(a) as being unpatentable over Gurtiss, III (US Pat. 5,389,368) as applied to claims 19, 22, 25, 27-28 above, in view of Burnham (WO98/02546), is herein withdrawn in light of the amendment of claim 19 to require the expression of the nucleic acid to be expressed by the host and not the attenuated strain, to which the strain is administered, as well as the claims now require the attenuated strain to be an auxotrophic bacterium (amended claim 19).

1. ***Rejections Withdrawn:*** Claim 19 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,5,8,10, 15, and 17 of U.S. Patent No. 6,872,814, has been obviated through submission of an effective terminal disclaimer.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 19-22, 24-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Murdin et al (US Pat. 6,693,087, effective filing date August 20, 1998) in light of WO92/11361.

Murdin et al disclose and claim an expression vector (see claim 8, col. 39) comprising an expression cassette (see col. 39, claim 7),which is formulated into a vaccine vector composition (see col. 40, claims 9) the nucleic acid sequence encoding a Chlamydia immunogens, to include trachomatis and pneumoniae immunogens (see col. 12, lines 23-31 and col. 39, claim 1) operatively linked to a control sequence in a plasmid (see col. 40, claim 9),

- wherein the expression control elements are for expression of the encoded immunogen in a mammalian cell, under control of a cytomegalovirus promoter (see col. 14, lines 24-38; Figure 3B, 3C);
- the vaccine vector (see col. 4, lines 36-37) in an immunogenic composition is disclosed to be an attenuated Salmonella typhimurium strain genetically engineered

for recombinant expression of heterologous antigens, used an oral vaccine (see col. 13, lines 49-55), and the attenuation is defined in light of WO92/11361 which shows Salmonella typhimurium auxotrophic attenuated strains (see WO92', page 4, paragraphs 3-4).

- The nucleic acid is disclosed/defined to encode a major outer membrane protein of Chlamydia (see col.3, lines 60-65 "MOMP" and col. 4, lines 1-25).

Murdin et al inherently anticipates the instantly claimed invention as now claimed, in light of the definition of the attenuated Salmonella typhimurium to include auxotrophic attenuated strains.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

4. Claims 19-22, 24-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Murdin et al (US Pat. 6,686,339, effective filing date August 20, 1998) in light of WO92/11361.

Murdin et al disclose and claim an expression vector (see claim 9, col. 31) comprising an expression cassette (see col. 31, claim 1),which is formulated into a vaccine vector composition (see col. 31, claim 10 and19) the nucleic acid sequence encoding a Chlamydia immunogens, to

include trachomatis and pneumoniae immunogens (see col. 12, lines 4-26 and col. 31, claim 1) operatively linked to a control sequence in a plasmid (see col. 31, claim 18),

- wherein the expression control elements are for expression of the encoded immunogen in a mammalian cell, under control of a cytomegalovirus promoter (see col. 31, claim 19; Figure 3B, 3C);
- the vaccine vector (see col. 4, lines 36-37 is disclosed to be an attenuated Salmonella typhimurium strain genetically engineered for recombinant expression of heterologous antigens, used an oral vaccine (see col. 13, lines 43-48), and the attenuation is defined in light of WO92/11361 which shows Salmonella typhimurium auxotrophic attenuated strains (see WO92', page 4, paragraphs 3-4).
- The nucleic acid is disclosed/defined to encode a major outer membrane protein of Chlamydia (see col.3, lines 62-67 "MOMP" and col. 4, lines 1-25 and all claims).

Murdin et al inherently anticipates the instantly claimed invention as now claimed, in light of the definition of the attenuated Salmonella typhimurium to include auxotrophic attenuated strains.

1. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594
2. Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 19, 24, 25, 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darji et al (1997) in view of Brey et al (US Pat. 5,919,663, filing date Jan. 30, 1995).

Darji et al teach and show an auxotrophic (aroA, see page 766, col. 1, paragraph 1) attenuated Salmonella typhimurium (title) for the transfer of plasmid DNA from the bacterial carrier to an immunocompetent host for vaccination of the host (see Summary, page 765) and induction of an immune response, wherein the attenuated strain of Salmonella plasmid comprises an expression control sequence from cytomegalovirus (see page 766, col. 1, paragraph 2) operatively linked to a nucleic acid coding sequence for a heterologous immunogenic polypeptide.

Darji et al teach the attenuated auxotrophic Salmonella bacterium to be a "highly versatile system for antigen delivery" (see Summary, page 765) which serves to carry an eukaryotic expression vector (see page 772, col. 2, paragraph 3) for induction of a strong antibody response by the infected host cell, but differs from the instantly claimed invention by failing to show the antigen to be a Chlamydia trachomatis antigen.

Brey et al teach and show an auxotrophic (see claims 19 and 27) Salmonella (see claims 21, 24-25) bacterium carrying the coding sequence for heterologous bacterial antigen, wherein the antigen is Chlamydia trachomatis antigen (see claim 6) in an analogous art for the purpose of producing, inducing and using the attenuated auxotrophic Salmonella typhimurium to induce an immune response against a Chlamydia trachomatis polypeptide antigen.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the composition of Darji et al which expresses heterologous bacterial polypeptide antigens through introduction and expression of an eukaryotic expression vector in a host with the Chlamydia trachomatis antigen coding sequence of Brey et al because both references utilize auxotrophic AroA Salmonella expression vectors for expression of a heterologous antigen, and Darji et al teaches a highly versatile system for antigen delivery to a host with to stimulate an immune response thereto and Brey et al teaches a nucleic acid coding sequence of Chlamydia trachomatis for expression from a Salmonella auxotrophic bacterium, the expressed polypeptide serving to induce an immune response to the heterologously expressed Chlamydial antigen.

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of producing an attenuated

strain of auxotrophic bacterium harboring a vector comprising a nucleic acid encoding at least one immune response inducting Chlamydia protein or fragment there of and a promoter operatively coupled to the nucleic acid molecule for expression of the Chlamydia protein or fragment thereof by cells of a host to which the strain is administered because Darji et al successfully induced a strong immune response to the bacterial antigen encoded by the eukaryotic expression system carried by the auxotrophic attenuated Salmonella typhimurium strain and teaches the Salmonella strain to be a highly versatile system for transfer and expression of plasmid DNA from the Salmonella to the host, and Brey et al teach a nucleotide sequence for incorporation into a Salmonella expression vector for induction of an immune response directed to a human pathogen, specifically Chlamydia trachomatis (see all Brey et al claims).

Darji et al in view of Brey et al obviate the instantly claimed invention as now claimed.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Numerous PG-Pub and issued patents to Brunham and Murdin are being cited and made of record (see US-PTO 892).

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
February 16, 2006

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